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Attorneys for Plaintiffs Merck & Cie, Bayer Pharma AG
and Bayer HealthCare Pharmaceuticals Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

MERCK & CIE, BAYER PHARMA AG, and
BAYER HEALTHCARE
PHARMACEUTICALS INC.,

Plaintiffs,

vs.

WATSON LABORATORIES, INC., and
ACTAVIS, INC.,

Defendants.

Case No. 2:13-cv-00990

**COMPLAINT FOR PATENT
INFRINGEMENT**

(JURY DEMAND)

Plaintiffs Merck & Cie, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc., for
their Complaint for patent infringement herein against Defendants Watson Laboratories, Inc. and
Actavis, Inc., allege as follows:

PARTIES

1. Plaintiff Merck & Cie (“Merck”) is a Swiss corporation having a principal place of business at Weissshausmatte 6460 Altdorf, Switzerland.

2. Plaintiff Bayer Pharma AG (“Bayer Pharma”), formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

4. On information and belief, Defendant Actavis, Inc. (“Actavis”) is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880. Defendant Actavis develops, manufactures, and markets generic pharmaceutical products through its operating subsidiary Defendant Watson Laboratories, Inc.

5. On information and belief, Defendant Watson Laboratories, Inc. (“Watson Labs.”) is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

6. On information and belief, Defendant Watson Labs. is a wholly-owned subsidiary of Defendant Actavis, and the two have common officers and directors.

7. On information and belief, Defendant Actavis directed, authorized, participated in, assisted and cooperated with Defendant Watson Labs. in all of the acts complained of herein. Hereinafter, Defendants Actavis and Watson Labs. are collectively referred to as “Watson.”

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendants Actavis and Watson Labs. by virtue of, *inter alia*, the fact that they regularly transact and solicit business in Nevada, have

1 consented to jurisdiction in Nevada in cases arising out of the filing of their ANDAs, and have
2 purposefully availed themselves of this forum such that they should reasonably anticipate being
3 haled into Court here.

4 10. On information and belief, Actavis has consolidated its activities and financial
5 results in its most recent SEC filings and Annual Report with, among other entities, Watson Labs.

6 11. On information and belief, Actavis and Watson Labs. earn revenue from the
7 distribution in Nevada of generic pharmaceutical products that are manufactured by Watson Labs.
8 On information and belief, various products for which Watson Labs. is the named applicant on
9 approved ANDAs are available at retail pharmacies in Nevada and elsewhere through a link
10 provided on Actavis' website.

11 12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and §
12 1400(b).

13 **BACKGROUND**

14 13. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No.
15 022574, for Safyral®, which contains as active ingredients drospirenone, 17 α -ethinyl estradiol,
16 and levomefolate calcium. Safyral® tablets have been approved by the United States Food and
17 Drug Administration ("FDA") to prevent pregnancy in women who elect to use an oral
18 contraceptive, and to provide a daily dose of folate supplementation. Safyral® tablets are sold in
19 the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 21
20 tablets comprising 3 mg of micronized drospirenone, 0.03 mg of micronized 17 α -ethinylestradiol,
21 and 0.451 mg levomefolate calcium plus 7 tablets comprising 0.451 mg levomefolate calcium.

22 14. On information and belief, Watson submitted to the FDA Abbreviated New Drug
23 Application ("ANDA") No. 203594 under the provisions of 21 U.S.C. § 355(j), seeking approval
24 to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic
25 version of Bayer HealthCare's Safyral® tablets.

26 15. On information and belief, the composition of the product that is the subject of
27 Watson's ANDA is for oral contraception in a human female and contains tablets comprising 3 mg
28 of drospirenone, 0.03 mg of 17 α -ethinylestradiol, and 0.451 mg levomefolate calcium, and tablets

1 comprising 0.451 mg levomefolate calcium.

2 16. On information and belief, Watson's ANDA seeks approval of a 28-day oral
3 contraceptive regimen that contains 21 tablets comprising 3 mg of drospirenone, 0.03 mg of 17 α -
4 ethinylestradiol, and 0.451 mg levomefolate calcium, and 7 tablets comprising 0.451 mg
5 levomefolate calcium (hereinafter "Watson's ANDA product").

6 17. On information and belief, on or about April 22, 2013, Watson sent a Notice Letter
7 to Plaintiffs Merck, Bayer Pharma, and Bayer HealthCare, purporting to comply with the
8 provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

9 18. The patent-in-suit is U.S. Patent No. 6,441,168 (the "'168 Patent") (attached hereto
10 as Exhibit 1). Inventors Rudolf Müller, Rudolf Moser, and Thomas Egger filed their application
11 for this patent on April 17, 2000. The '168 Patent was issued August 27, 2002. Merck & Cie is
12 the current owner of the '168 Patent.

13 19. Bayer Pharma is the exclusive licensee of the '168 Patent for the sectors of
14 gynecology and andrology, for the indications fertility control, hormone therapy, and hormone
15 replacement therapy (with the exception of oncological indications). Bayer Pharma is also the
16 exclusive licensee of the '168 Patent for the indications listed above as a primary indication in
17 combination with secondary indications within the same product.

18 20. Bayer HealthCare markets Safyral® in the United States under Bayer Pharma's
19 exclusive license.

20 **COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF**
21 **UNITED STATES PATENT NO. 6,441,168**

22 21. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth
23 herein.

24 22. On information and belief, Watson's ANDA product infringes one or more claims
25 of the '168 Patent.

26 23. The '168 Patent covers Bayer HealthCare's Safyral® tablets and has been listed for
27 the product in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations ("the
28 Orange Book").

1 24. On information and belief, Watson submitted its ANDA to the FDA for the purpose
2 of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
3 importation of Watson's ANDA product before the expiration of the '168 Patent.

4 25. On information and belief, Watson made and included in its ANDA a certification
5 under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '168 Patent is invalid,
6 unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or
7 importation of Watson's ANDA product.

8 26. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval
9 to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's
10 ANDA product before the expiration of the '168 Patent, Watson has committed an act of
11 infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial
12 manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product will also
13 infringe one or more claims of the '168 Patent.

14 27. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271e(4), including an
15 Order of this Court that the effective date of any approval relating to Watson's ANDA shall be a
16 date which is not earlier than April 17, 2020, the current expiration date of the '168 Patent, or any
17 later date of exclusivity to which Plaintiffs become entitled.

18 28. On information and belief, when Watson filed its ANDA, it was aware of the '168
19 Patent and was aware that the filing of its ANDA with the request for its approval prior to the
20 expiration of the '168 Patent constituted an act of infringement of the '168 Patent.

21 29. This case is an exceptional one, and Plaintiffs are entitled to an award of their
22 reasonable attorney fees under 35 U.S.C. § 285.

23 **PRAYER FOR RELIEF**

24 **WHEREFORE**, Plaintiffs respectfully request the following relief:

25 A. Judgment that Watson has infringed one or more claims of the '168 Patent by filing
26 its ANDA relating to Watson's ANDA product containing drospirenone, ethinylestradiol, and
27 levomefolate calcium;

28 B. A permanent injunction restraining and enjoining Watson and its officers, agents,

1 attorneys and employees, and those acting in privity or concert with it, from engaging in the
2 commercial manufacture, use, offer to sell, or sale within the United States, or importation into the
3 United States, of Watson's ANDA product;

4 C. An order that the effective date of any approval of Watson's ANDA relating to
5 Watson's ANDA product containing drospirenone, ethinylestradiol, and levomefolate calcium, be
6 a date which is not earlier than the expiration date of the '168 Patent or any later date of
7 exclusivity to which Plaintiffs become entitled;

8 D. Damages from Watson for any commercial activity constituting infringement of the
9 '168 Patent; and

10 E. Such other and further relief as the Court may deem just and proper.

11 **JURY DEMAND**

12 Plaintiffs hereby demand a jury trial on all issues so triable.

13 Dated: this 4th day of June 2013.

14 LEWIS AND ROCA LLP

15 By: /s/ Jonathan W. Fountain

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